

Application Number: 10/649,134

Reply To Office Action Of OCTOBER 19, 2005

**Amendments to the Specification**

Please replace paragraph [00001] with the following amended paragraph:

[00001] This application claims priority to U.S. Provisional Patent Application No. 60/406,694, filed August 29, 2002, which is hereby incorporated by reference in its entirety. This application is also related to U.S. application Ser. No. [10/\_\_\_\_\_] 10/649,396 filed August 27, 2003, ~~(Attorney Docket No. P-5369B)~~, and U.S. application Ser. No. [10/\_\_\_\_\_] 10/649,395 filed August 27, 2003, ~~(Attorney Docket No. P-5370-7767-174190)~~ both filed concurrently herewith.

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Please replace paragraph [00002] with the following amended paragraph:

[00002] The present invention relates to a method and device for abrading the skin. More particularly, the invention is directed to a method of abrading the stratum corneum by employing a device imparting a rotary movement to an abrading surface.

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Please replace paragraph [00005] with the following amended paragraph:

[00005] For topical delivery of vaccines, the epidermis itself is a particularly desirable [taget] target as it is rich in antigen presenting cells. In comparison, the dermal layer below the epidermis contains fewer antigen presenting cells. Furthermore, the stratum corneum and epidermis do not contain nerves or blood vessels, so this method has the advantage of being essentially painless and blood-free while giving access to the skin layers capable of responding to the antigen.

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Please replace paragraph [000054] with the following amended paragraph:

[000054] The abrading surface 5 can be rectangular, circular, or any other shape. Depending upon the drug or vaccine to be delivered and the amount of abrasion desired, the array of microprotrusions 14 on the abrading surface 5 may have varying designs that may be beneficial for rotary delivery devices. The tips of the microprotrusions may be in the same plane or their heights may vary due to the amount of abrasion desired. Each microprotrusion has at least one scraping edge and is of a length to penetrate the stratum corneum without piercing the stratum corneum, and depending on the desired amount of abrasion, the scraping edges of an array or portion of an array may point in the same or different directions.

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Please replace paragraph [000057] with the following amended paragraph:

[0057] A handle 6 is attached to arcuate base 4. Handle 6 may be glued (e.g., with epoxy) to the underside 4c of base 4, may be a snap or friction fit, or be integrally molded. Underside 4c of base 4 may be flush with mushroom-like crown 4b or extend beyond the mushroom-like crown, or may be integrally formed as an extension of base 4. The lower end 6b of handle 6 is wider than the shaft of handle 6. Lower end 6b includes an impression 6d that serves as a thumb rest for a person administering the substance to firmly grasp microabrader device 2. In addition, protrusions 8 are formed on the outside of handle 6 to assist a user in firmly gripping handle 6 when using the device 2 against a patient's epidermis.

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Please replace paragraph [000065] with the following amended paragraph:

[000065] Looking at FIGS. 7 and 8, a rotary delivery device 30 is shown according to one embodiment of the invention. FIG. 7 is a perspective view of a device depicted with a see-through housing so that the mechanical components can be viewed, while FIG. 8 is a sectional view of rotary device 30. Rotary delivery device 30 includes a housing 32, which is cylindrical in this preferred embodiment. The housing need not be circular, as rectangular, square, oval or other shapes may be used. Housing 32 has a longitudinal axis, is generally hollow and is preferably of a shape about which a user's fingers can grasp for added control. The top 34 of housing 32 has an opening 36 through which an interlock mechanism, such as button 38 that is integrally attached to a longitudinally movable rod 38' moves upon activation. In a preferred embodiment, the top of button 38 extends through opening 36 while a base 37 of button 38 adjacent rod 38' is located inside housing 32. Base 37 has a larger width/diameter than the top of the base. The width/diameter of the base is approximately equal to the interior of housing 32. The thickness of base 37, as well as [it] its width, is designed to provide a strong, stable support for the activation means or push button 38. Rod 38' preferably is integrally attached to the base 37 of button 38 inside of housing 32

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Please replace paragraph [000070] with the following amended paragraph:

[000070] While the interlock mechanism illustrated is a button disposed perpendicularly to the abrading surface, other interlock mechanisms may be employed. For example, a lever disposed about the housing of the rotary device may be pushed approximately parallel to skin held in place by the stationary housing. The lateral pushing of the lever would deactivate a spring causing the abrading surface 5 held within the stationary housing to rotate. Similarly, a handle projecting from the side of the stationary housing may be a lever, button or rotary motion that deactivates the spring causing the abrading surface 5 to rotate.

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Please replace the Abstract {Paragraph [000091]} with the following amended paragraph:

[000091] A method and device for the delivery of a substance into skin via the rotational movement of a microabrader device reduces the effects of operator variability. The method includes applying a substance to an area of a patient's skin through the rotational movement of microprotrusions which may be. ~~The movement of the microprotrusions can be~~ imparted by a spring device ~~or the like~~ present in the microabrader device or the motion of the operator through the handle of the microabrader device. ~~The rotational motion localizes the administration of the drug or vaccine dosage in the abraded skin area.~~ The device may further ~~can~~ include means system and methods for monitoring pressure of the device against the skin and thereby promote consistency between applications and control of penetration depth. The delivered substance, ~~drug or vaccine~~ may be placed on the microprotrusions and a reconstituting liquid included in the microabrader device.